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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/560,289 | 05/26/2006 | Robert J Benkowski | 021906-024US | 3187 |

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| EXAMINER | |
|---|---|
| NARAYANASWAMY, SHUBATRA | |
| ART UNIT | PAPER NUMBER |
| 3762 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 06/09/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

hoip@lockelord.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/560,289 | BENKOWSKI ET AL. | |
| | Examiner | Art Unit | |
| | SHUBATRA NARAYANASWAMY | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,6,8,10-12,16,17 and 20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8,10-12,16,17 and 20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. Claim 12 is amended.

2. The 112 rejection of claim 12 is withdrawn.

3. Claims 20-31 have been added.

### *Claim Rejections - 35 USC § 101*

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 6, 8, 10-12, 16, and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a judicial exception to 35 U.S.C. 101 (an abstract idea) and is not directed to a practical application of such judicial exception because the claim does not require any physical transformation and the invention as claimed does not produce a useful, concrete, and tangible result. The claimed blood pump is not necessarily a machine. It could be the heart, which is also a blood pump, or a mechanical blood pump. Further, claim 1 does not specify what "controlling" the blood pump entails. The broadest reasonable interpretation of this limitation includes turning the pump on or off, simply allowing the pump to work, or preventing the pump from working. A particular machine is the one and only machine for which the claim will work to the exclusion of all other machines.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 6, 8, 10-12, 16, and 17 rejected under 35 U.S.C. 102(b) as being anticipated by Ash (US 4995268).

**As to claim 1**, Ash discloses a method of controlling a blood pump, comprising: analyzing an instantaneous flow waveform in both the time domain and frequency domain; and controlling the pump in response thereto (col. 12 ll. 5-70).

**As to claim 6**, Ash discloses the method of claim 1, in which the analysis of the flow wave form determines a suction boundary condition (col. 12 ll. 5-70).

**As to claim 8**, Ash discloses the method of claim 6, further comprising boundary conditions for maximum power, maximum speed, minimum speed, minimum flow, change in flow peak-to-peak amplitude over change in pump speed, change in mean flow over change in pump speed, and change in pump power over change in pump speed (col. 12 ll. 5-70).

**As to claim 10**, Ash discloses the method of claim 6 or claim 8 where the boundary conditions become control parameters for closed loop control (col. 12 ll. 5-70).

**As to claim 11**, Ash discloses the method of claim 6 or claim 8 where the boundary conditions cause the control system to clamp pump speed, and where upper boundary conditions do not allow the speed to be increased further while lower boundary

conditions do not allow the speed to be decreased further (col. 12 ll. 5-70).

**As to claim 12**, Ash discloses the method of claim 6 or claim 8 where the boundary condition of suction causes a predetermined decrease in speed then periodically attempts to return to the desired control mode at predetermined intervals (col. 12 ll. 5-70).

**As to claim 16**, Ash discloses the method of claim 1 where a fail-safe feature to switch to the Constant Speed mode is automatically enabled in the event of a lost, erroneous, or compromised flow signal (col. 10 ll. 10-20).

**As to claim 17**, Ash discloses the method of claim 1 where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform (col. 12 ll. 5-70).

**As to claim 20**, Ash discloses a method of controlling a blood pump, comprising:

receiving, in a controller, a flow signal from an implanted flow sensor, the flow signal indicative of an instantaneous flow waveform;

analyzing the flow waveform in both the time domain and frequency domain; and

outputting, from the controller, a control signal to control an implanted blood pump in response to the analysis of the flow waveform (col. 12 ll. 5-70).

**As to claim 21**, Ash discloses the method of claim 20, in which the analysis of the flow waveform determines a suction boundary condition (col. 12 ll. 5-70).

**As to claim 22**, Ash discloses the method of claim 21 where the boundary condition becomes control parameters for closed loop control (col. 12 ll. 5-70).

**As to claim 23**, Ash discloses the method of claim 21 where the boundary condition causes the control system to limit pump speed, and where upper boundary conditions do not allow the speed to be increased further while lower boundary conditions do not allow the speed to be decreased further (col. 12 ll. 5-70).

**As to claim 24**, Ash discloses the method of claim 21 where the boundary condition causes a predetermined decrease in speed then periodically attempts to return to the desired control mode at predetermined intervals (col. 12 ll. 5-70).

**As to claim 25**, Ash discloses the method of claim 20, in which the analysis of the flow waveform determines boundary conditions for suction, maximum power, maximum speed, minimum speed, minimum flow, change in flow peak-to-peak amplitude over change in pump speed, change in mean flow over change in pump speed, and change in pump power over change in pump speed (col. 12 ll. 5-70).

**As to claim 26**, Ash discloses the method of claim 20 where a fail-safe feature to switch to a Constant Speed mode is automatically enabled in the event the flow signal is lost, erroneous, or compromised (col. 12 ll. 49-55).

**As to claim 27**, Ash discloses the method of claim 26 where the quality of the flow signal is determined by the frequency domain analysis of the real-time flow waveform (col. 12 ll. 5-70).

**As to claim 28**, Ash discloses the method of claim 20 wherein the control signal from the controller is adapted to a patient's individual physiology in response to speed variations (abstract).

**As to claim 29**, Ash discloses the method of claim 20 further comprising analyzing the flow waveform based on both instantaneous and mean values (col. 5 ll. 63-65)

**As to claim 30**, Ash discloses the method of claim 20 wherein the control signal from the controller is adapted to a patient's individual physiology in response to suction detection events (col. 5 ll. 63-65)

***Response to Arguments***

7. Applicant's arguments filed 03/03/2010 have been fully considered but they are not persuasive. As to claims 1, 6, 8, 10-12, 16, and 17 as rejected under 35 U.S.C. 101, the claims do not use a machine to analyze the waveform data, do not have a source for the waveform, and are not explicitly tied to a particular machine.

8. As to claims 1, 6, 8, 10-12, 16, and 17 as rejected under U.S.C. 102, Ash discloses analyzing a flow rate, or units/time, which is synonymous with frequency. Further, the Applicant does not teach any other definition of 'frequency'. The Applicant also does not teach an explicit definition of 'suction boundary condition', so this term is interpreted by the Examiner to include any boundary condition which affects the blood pump. Ash discloses measuring the instantaneous blood flow rate at four different times and averaging the rates. Ash also teaches measuring the change in average

blood flow (col. 5 ll. 63-65) over change in pump rate (col. 11 ll. 5-36). As to claim 12, Ash teaches automatically delivering defined amounts of fluid into the arterial line on present intervals if a patient reaches a 'dry weight', which can be considered an erroneous signal (col. 12 ll. 49-55).

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUBATRA NARAYANASWAMY whose telephone number is (571)-270-7406. The examiner can normally be reached on M-F, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George Manuel/
Primary Examiner, Art Unit 3762

/S. N./
Examiner, Art Unit 3762